



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. FDA-2016-N-1745]

Maximum Civil Money Penalty Amounts; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or we) is amending its regulations to remove the maximum civil money penalties table associated with statutory provisions. This information will be included in the Department of Health and Human Services' (HHS) regulations. We are taking this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 2015.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Jarilyn Dupont, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4248, Silver Spring, MD 20993-0002, 301-796-4830.

SUPPLEMENTARY INFORMATION: In the Federal Register of February 3, 2014 (79 FR 6088), FDA issued a new regulation in 21 CFR 17.2 to adjust for inflation the maximum civil money penalty amounts for the various civil money penalty authorities within our jurisdiction and other matters.

FDA is amending 21 CFR 17.2 to remove the maximum civil money penalties table associated with statutory provisions authorizing civil money penalties under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) or the Public Health Service Act (PHS Act). The Federal Civil Penalties Inflation Adjustment Act of 2015 (Pub. L. 114-74, November 2, 2015) requires each Agency to adjust each civil money penalty provided by law within the jurisdiction of that Agency in one regulation. In accordance with this requirement, HHS is issuing a regulation that, in a consolidated table, adjusts the maximum civil money penalties associated with statutory provisions authorizing such penalties for all HHS Agencies. Because this consolidated table of these maximum civil money penalties, including those authorized under the FD&C Act and the PHS Act, can be found at 45 CFR 102.3, we are including a cross-reference to 45 CFR 102.3 in our regulations. We are taking this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 2015.

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comments are unnecessary because the amendments to the regulations provide only technical changes to remove and update information and are nonsubstantive.

List of Subjects in 21 CFR Part 17

Administrative practice and procedure, Penalties.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 17 is amended as follows:

PART 17--CIVIL MONEY PENALTIES HEARINGS

1. The authority citation for part 17 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa-28; 5 U.S.C. 554, 555, 556, 557.

2. Revise § 17.2 to read as follows:

§ 17.2 Maximum penalty amounts.

The maximum civil money penalties associated with the statutory provisions authorizing civil money penalties under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act can be found at 45 CFR part 102. The table of these maximum civil money penalties can be found at 45 CFR 102.3.

Dated: July 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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